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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,953	06/24/2003	Steven C. Quay	02-03US	6874

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EXAMINER	
KOSAR, ANDREW D	
ART UNIT	**PAPER NUMBER**
1654	
MAIL DATE	**DELIVERY MODE**
05/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/601,953	QUAY, STEVEN C.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-4,10-19,24,25,30-43,45,46,48-82 and 89-92* is/are pending in the application.

4a) Of the above claim(s) *18,19,24,25 and 48-81* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,10-17,30-43,45,46,82 and 89-92* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendments/Arguments

Applicant's amendments and arguments filed February 28, 2007 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Applicant confirms the election of Group I and SEQ ID NO:4. The requirement is still deemed proper and made FINAL.

Claims 18, 19, 24, 25 and 48-81 remain withdrawn from consideration for the reasons of record.

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 10-17, 30-43, 45, 46, 82 and 89-92 are/remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons of record and those set forth below. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues that the claims have been amended to recite structural components of the permeabilizing peptide and argues that the biologically active agents are adequately described by such terms as 'antihistamine', 'anti-hypertensive agent', etc. as in claim 13, defining classes of compounds that can be used.

Respectfully, the examiner disagrees. The claims, as they have been currently amended, do not limit the permeabilizing peptide to any specific peptide, or peptides, but rather to peptides

of 4-25 amino acids and "including one or more contiguous sequence elements" of the recited sequences, e.g. SEQ ID NO:4. This, in essence, embraces peptides having as few as two amino acids, and possibly even one single amino acid, from any of the sequences. Here, the claim language presented provides the broadest reasonable interpretation of the claims to include a dipeptide as a contiguous sequence element. Furthermore, this interpretation is supported by the dependent claims having such sequences as VR(I,V,A)P, which are broader in scope than the independent claim VRIP. Thus, the claims still embrace a myriad of peptides 4-25 amino acids in length having as small as a dipeptide of any of the recited sequences.

With regards to the biologically active agent, such descriptions as 'cilliostatic agent', 'antiallergy agent', 'degredative enzyme inhibitory agent', etc. describe the compounds functionally, and while this may be a means of classification of the compounds, it does not provide structural information, or provide description of which compounds have been contemplated, as does such descriptive claims as, e.g. claim 15 which describes therapeutic peptides or proteins.

In combination, the claims describe a myriad of compositions while the specification provides so few examples to adequately provide descriptive support for the entirety of the genus.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated, "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re*

Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated, "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical

cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention*. While all of the factors have been considered, a sufficient amount for a *prima facie* case are presented.

In the instant case, the claims are drawn to a myriad of peptides and compositions comprising proteins or fragments of proteins or analogs by substitution/deletion/insertion of the protein or fragment, where the protein is a JAM, occludin or claudin. The composition must further comprise a biological active agent and additional delivery enhancing agents.

(İ) Level of skill and knowledge in the art:

Peptide fragments are known in the art, and the art recognizes JAM, occludin and claudin peptides. The art generally recognizes drugs and the classes, as well as the general classes of pH control agent, vasodilator, etc. which are the enhancing agents. However, the level of skill and knowledge in the art is low with regards to the myriad of combinations and the *a priori* knowledge that the virtually limitless number of combinations would function as claimed. Although the independent claims have been amended to recite peptide sequences, the claim language does not require the selection of a single peptide or combination of peptides, but rather allows for selection of a fragment- a 'contiguous sequence element'.

(2) Partial structure:

The claims provide structures for various elements, however no single claim fully defines one composition. The specification provides various peptide fragments with the asserted activity and provides several closely related compositions in the examples. However, most claims do not provide structure, but rather rely on the function, e.g. permeabilizing peptide, a ciliostatic agent, a vasodilatory agent, etc. Although the independent claims have been amended to recite peptide sequences, the claim language does not require the selection of a single peptide or combination of peptides, but rather allows for selection of a fragment- a 'contiguous sequence element', and thus the claims embrace peptides beyond that of a discrete peptide such as SEQ ID NO:4.

(3) Physical and/or chemical properties and (4) Functional characteristics:

Although the claims have been amended to recite sequences for the permeabilizing peptide, no specific structural element is coupled to the function, as the claims allow for fragments of the sequences, and there is no disclosure of structure essential to the function. The additional elements, e.g. ciliostatic agent, vasodilatory agent, must also function as mucosal delivery-enhancing agent, which is generally a function not attributed to such compounds. Furthermore, human occludin peptide sequence SEQ ID NO:32-35 or 42, and the fragments thereof, are required to inhibit claudin epithelial membrane protein.

(5) Method of making the claimed invention:

Methods of making compositions are known in the art, however the methods of making the myriad of compositions as claimed and having the requisite activity are beyond those known in the art. Furthermore, it is beyond that of the skill of the artisan to make peptides a human occludin peptide sequence SEQ ID NO:32-35 or 42 that will inhibit claudin epithelial membrane protein.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that the claims are broad generics with respect to all possible peptides, fragments and compositions encompassed by the claims. The possible variations in the structure of the peptide and the elements in the composition are limitless. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence."

MPEP § 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide a sufficient number of species of peptide with the requisite activity or compositions thereof. While having written description of the peptides shown to have the requisite activity and the compositions identified in the specification tables and/or examples, the specification is void of a sufficient number of species to show applicant was in possession of the genus of peptide and composition as instantly claimed.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 10-17, 30-43, 45, 46, 82 and 89-92 are/remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant argues that the claims have been amended to overcome the 112 2nd rejections, however, respectfully, Applicant has not addressed claim 15.

Claim 1 and 82 recite, "contiguous sequence element", which is not defined in the specification in such a manner that one would understand whether the claims are drawn to the combinations of the recited sequences or whether the peptide merely require a fragment of any one or more of the sequences, e.g. 2 residues from SEQ ID NO:4 and 3 from SEQ ID NO:63, or only 2 from SEQ ID NO:4. This issue is further compounded in view of the dependency of claim 11, which allows for the peptide VR(I,L,A)P, which is not found within claim 1, but rather has two contiguous sequence elements of SEQ ID NO:4.

Alternatively, claims 11 and 92 lack clear antecedent basis, as the independent claims do not allow for the peptides to be substitution variants.

Claim 15 lacks clear antecedent basis. Claim 15 includes compounds which are not therapeutic peptides or proteins, *per se*, and thus the claim lacks clear antecedent basis, and further, it is unclear how Applicant is intending to define a peptide or protein as many of the recited compounds are not peptides or proteins, e.g. estrogen, testosterone, ciclopirox, midazolam, opiods, etc.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Applicant argues that the claim amendments distinguish the claims from the prior art. Respectfully, the examiner disagrees. Here, the teachings of Blaszczyk-Thurin or Blaschuk still read upon the claims, as the claims are not limited to only conjugates of the recited sequences.

Claims 82 and 89-92 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by BLASZCZYK-THURIN (WO 00/27420 A1) for the reasons of record and those set forth below.

Blaszczyk-Thurin teaches SEQ ID NO:119 (GLDLLGDVRIPVVRR) (Table 1), which is a 15 amino acid sequence which comprises VRIP. Because the peptide has the requisite structural element, in inherently must function as claimed.

Claims 1-4, 12-14, 16, 17, 32-41 and 82 are rejected under 35 U.S.C. 102(a) as being anticipated by BLASCHUK (US Patent 6,391,855).

Blaschuk teaches a JAM peptide comprising JAM CAR sequence SFTIDPKSG (SEQ ID NO:2) (claim 1), which is interpreted as a peptide having one or more contiguous sequence elements of instant SEQ ID NO:54 (the dipeptide TI), in a pharmaceutical composition with a pharmaceutically acceptable carrier (claim 9) and a drug (claim 10). In looking to the specification, Blaschuk teaches that, "virtually any drug may be administered in combination with a modulating agent as described herein" (column 23, lines 51-52) and provides a myriad of drugs that can be used, including taxol, mitomycin C, indomethacin and ibuprofen, as well as generic antifungals, analgesics, vasodilators, narcotic antagonists (e.g. column 23, line 53 to column 24, line 6). The peptide of Blaschuk is an extracellular domain of murine JAM.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Applicant argues that since the claims have been amended to overcome the 102 rejections, allegedly rendering the primary references deficient, the 103 rejections are overcome, and that the secondary references do not rectify the issues.

Respectfully, the examiner disagrees. The rejections under 35 USC § 102 have been maintained above, and thus the rejections have not been overcome and the references are still valid. Accordingly, the *prima facie* cases of obviousness is still appropriate as the amendments do not overcome the previous rejection.

Claims 1-4, 12-17, 32-43 and 82 are rejected under 35 U.S.C. 103(a) as being obvious over Blaschuk, *supra*, in view of PLATZ (US Patent 5,345,562).

The teachings of Blaschuk are presented *supra*.

Platz teaches micronized polypeptide drug formulations as powders suitable for aerosol administration (e.g. column 2, lines 13-16). Platz teaches EPO, HGH, TPA, PDGF, TGF-β1,2 and 3, TGF-α, IGF-1 and 2, MGCSF, insulin, interleukin 1-7, interferon-α and –β (column 2, lines 31-32).

The difference between Blashchuk and the instant claims, is that while Blaschuk teaches the composition can have any drug or therapeutic agent, it does not teach the peptide.

It would have been obvious to have formulated the composition of Blaschuk with the peptides of Platz, as Blaschuk teaches any drug can be formulated in the composition.

One would have been motivated to have selected any peptide or protein, including the peptide drugs of Platz, because Blaschuk teaches the any drug can be formulated in the composition, and to increase the transcellular transport of the drugs of Platz.

One would have had a reasonable expectation for success in making the formulation, as Blaschuk teaches the composition can be formulated with any drug, and because combining elements in a formulation is a technique widely practiced in the medicinal arts.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Applicant argues that the amendments filed overcome the obviousness type double patenting. Respectfully, the examiner disagrees. While Applicant has included some structural elements to further define the permeabilizing peptide, the prior art provides such peptides as embodiments which provide support for the claims, and thus the rejections have not been overcome.

Claims 1-4, 10-14, 16, 17, 30-43, 82 and 89-92 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-62 of copending Application No. 10/840,536 (QUAY(2), US 2004/02586663 A1; amended claim set of 8/15/06).

Quay(2) teaches compositions which are of an overlapping, if not commensurate scope, where the composition is interferon-α with one or more mucosal delivery agents, formulated for nasal delivery as a powder or spray (claims 2-3), comprising mucosal delivery-enhancing agents which overlap with the instant composition (e.g. claim 19), where the mucosal delivery-enhancing agent is a JAM protein (claim 33). In looking to the specification for JAM proteins which provide support for the claims, Quay(2) specifically identifies the peptides of the instant application as JAM peptides (e.g. paragraphs [0199] and [0200]).

This is a provisional obviousness-type double patenting rejection.

Claims 1-4, 10-14, 16, 17, 30-43, 82 and 89- 92 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-50 and 53-57 of copending Application No. 10/462,452 (Quay(3), US 2004/0037809 A1; amended claim set of 10/10/06).

Quay(3) teaches compositions which are of an overlapping, if not commensurate scope, where the composition is interferon-β formulated for mucosal delivery with mucosal delivery-enhancing agents, e.g. aggregation inhibitory agent, ciliostatic agent, mucolytic agent or modulatory agent of epithelial junction physiology (e.g. claim 17). In looking to the specification for modulatory agent of epithelial junction physiology which provide support for the claims, Quay(3) provides a list of peptides, including JAM-1 and more specifically VRIP (paragraph [0247]).

This is a provisional obviousness-type double patenting rejection.

Claims 1-4, 10-14, 16, 17, 30-43, 82 and 89-92 are directed to an invention not patentably distinct from claims 1-62 of commonly assigned 10/840,536, for the reasons set forth *supra*.

Claims 1-4, 10-14, 16, 17, 30-43, 82 and 89-92 are directed to an invention not patentably distinct from claims 1-50 and 53-57 of commonly assigned 10/462,452, for the reasons set forth *supra*.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 10/840,536 and 10/462,452, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that

the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Applicant is reminded that due to Applicant's prolific Patent and Application portfolio, the burden is shifted to Applicant to identify all relevant Applications and Patents and to include said Applications and Patents on any terminal disclaimer filed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 18, 19, 24, 25 and 48-81 drawn to an invention nonelected with traverse in the reply filed on February 28, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew D Kosar, Ph.D.
Patent Examiner
Art Unit 1654

CECILIA TSANG
SUPERVISORY PATENT EXAMINER